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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,610	01/08/2004	Alfonzo T. Perez	C-3158	7155

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,610	PEREZ ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 18, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an angiotensin converting enzyme ("ACE") inhibitor, an aldosterone antagonist and a loop diuretic for reducing the number of non-fatal hospitalizations, classified in class 514, various subclasses depending on the specific active agents involved.

Group II, claim 19, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and a loop diuretic for reducing the death rate for deaths resulting from congestive heart failure, classified in class 514, various subclasses depending on the specific active agents involved.

Group III, claim 20, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in subjects having a left ventricular ejection fraction greater than 26%, classified in class 514, various subclasses depending on the specific active agents involved.

Group IV, claim 21, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in subjects having a

left ventricular ejection fraction greater than 26%, classified in class 514, various subclasses depending on the specific active agents involved.

Group V, claims 22-23, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and a loop diuretic for suppressing a clinically significant cough due to elevated pulmonary arterial pressure in a subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group VI, claim 25, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin for providing a statistically significant reduction in death rate, classified in class 514, various subclasses depending on the specific active agents involved.

Group VII, claim 26, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin for providing a statistically significant reduction in the number of non-fatal hospitalizations, classified in class 514, various subclasses depending on the specific active agents involved.

Group VIII, claim 27, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin for decreasing blood N-terminal atrial natriuretic factor level in a subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group IX, claim 28, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic

and digoxin for providing a decrease in blood pro-collagen type III amino-terminal pro-peptide level in a subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group X, claim 29, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin for providing a an increase in left ventricular ejection fraction in a subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group XI, claim 32, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the subject is classified in the New York Heart Association class III or class IV, classified in class 514, various subclasses depending on the specific active agents involved.

Group XII, claim 33, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the subject has a left ventricular ejection fraction greater than about 26%, classified in class 514, various subclasses depending on the specific active agents involved.

Group XIII, claim 34, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the subject has a left ventricular ejection fraction less than about 26%, classified in class 514, various subclasses depending on the specific active agents involved.

Group XIV, claim 35, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the subject is susceptible to or is suffering from a clinically significant cough due to elevated pulmonary arterial fibrosis or low levels of pulmonary blood pressure, classified in class 514, various subclasses depending on the specific active agents involved.

Group XV, claim 37, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin for reducing the death rate or number of non-fatal hospitalizations in a subject, where the subject is classified in the New York Heart Association class III or class IV, classified in class 514, various subclasses depending on the specific active agents involved.

Group XVI, claim 38, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the therapy also results in a decrease in blood N-terminal atrial natriuretic factor level in a subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group XVII, claim 39, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the therapy also results in a decrease in blood pro-collagen type III amino-terminal pro-

peptide level in the subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group XVIII, claim 40, drawn to a combination therapy for treating a cardiovascular disorder comprising administering an ACE inhibitor, an aldosterone antagonist and optionally, a loop diuretic for reducing the death rate or number of non-fatal hospitalizations in a subject, where the therapy also results in a decrease in blood brain natriuretic peptide levels in the subject, classified in class 514, various subclasses depending on the specific active agents involved.

Group XIX, claims 61-64, drawn to a composition comprising an ACE inhibitor, an aldosterone antagonist, a loop diuretic and digoxin, classified in class 514, various subclasses depending on the specific active agents present.

Linking Claims

Claims 1-17, 30, 31, 36 and 41-60 link inventions XI-XVII and claim 24 links inventions VI-X. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Notice of Right to Rejoin Inventions

The Examiner has required restriction between product and process claims. Where applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Inventions are unrelated if it can be shown that they are not capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01) and/or one or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

Groups I-XIX involve treatments of cardiovascular disorders in separate and different patient populations and for different therapeutic endpoints or purposes which support the Examiner's finding. Further, the objective of the methods could be accomplished by the use of any number of a different active agents. For example, the drug combination of Group XIX could be used for a separate and different therapeutic purpose such as the mere treatment of hypertension and congestive heart failure where no hospitalization or threat of death is involved. Also, a drug combination for the treatment of a cardiovascular disorder in a subject for reducing the death rate or the number of non-fatal hospitalizations as compared to mono-therapy could be accomplished through the use of various active agents not required in the present combination of Group XIX, such as a combination of a beta adrenergic blocking agent, such as propranolol, and a non-loop diuretic agent, such as hydrochlorothiazide. Therefore, each of the inventions of

Groups I-XVIII are unrelated except for the fact that each is directed to a treatment method and the combination of Group XIX is unrelated to any one of the inventions I-XVIII.

Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicants traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Claim Observation

An action on the merits of the claims in this action, which is a finding of a lack of a single general inventive concept, is not proper. The Examiner wishes to note, however, that in an action on the merits, claims 25-29 and 38-40 would be objectionable because these claims are improper multiple dependent claims in that they do not depend on the other claims in the alternative only and would thus be withdrawn from further consideration in such an action on the merits, (MPEP § 608.01(n) and 37 C.F.R. § 1.75(c)).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Raymond J Henley III
Primary Examiner
Art Unit 1614

June 23, 2007